REMARKS

The following remarks are in response to the Non-Final Office Action mailed on February 29, 2008. Claims 1-24 are canceled. Claims 25-27 are amended and currently pending. Claims 25-27 stand rejected but reconsideration of the application in view of the amendments and the following remarks is respectfully requested.

I. Objection of the Drawings

The drawing for Figure 4 is objected to as poor quality in that the differences between the copy of the photo of before treatment and the photo after treatment cannot be seen. In order to expedite prosecution, Figure 4 has been canceled without prejudice.

It is respectfully requested that the objection to the drawings be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 25-27 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The examiner states that there is no support for the limitation that "at least 10% (w/v) of the ascorbic acid" be pretreated ascorbic acid and that paragraph 00028 of the specification indicates that at least about 10% of the ascorbic acid present may be pretreated ascorbic acid.

The claims have been amended to recite "at least 10%". It is respectfully requested that the rejection of claims 25-27 under 35 U.S.C. §112, first paragraph be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 25-27 are rejected under 35 U.S.C. §112, second paragraph, as indefinite because while the claim recites a composition having a pH of about 3.5 to about 4.1, the only components identified in the body of the claim are water, glucosamine and ascorbic acid and with such components it is unclear how the pH can be as recited.

It is respectfully submitted that the claims recite a composition "having a pH of about 3.5 to about 4.1 and *comprising*..." certain ingredients. The "comprising" language allows for the inclusion of materials besides those specifically recited. One would understand from the claim what the composition covers and one knows how to accomplish the claimed pH range. Also, the claims must be read in light of the specification and the composition as claimed is clear from the specification.

However, in order to expedite the prosecution of the application, the claims have been amended to clearly recite a pH adjustment.

The examiner also rejected claim 26 as unclear saying that it is unclear how the composition of claim 25 can be made by the method of claim 26 as the pH range in claim 26 is narrower than that recited in claim 25.

The examiner is thanked for the helpful suggestion. The claim has been amended to recite the narrower pH of the composition of claim 26.

In view of these amendments and remarks, it is respectfully requested that the rejections of claims 25-27 under 35 U.S.C. §112, second paragraph, as indefinite be withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 103(a)

Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Murad in view of Schinitsky et al., Herstein, Bassford et al., Ptchelintsev and EP 0 771 557.

The examiner asserts that Murad teaches a composition for treatment of skin overexposed to sun and wrinkles and comprising glucosamine (about 3-17 percent) and ascorbic acid (about 5 to 50 weight percent), as pastes, cream, gel, or ointment. The examiner states that Murad teaches that gluscosamine assists in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkles and the ascorbic acid inhibits collagenase and elastase enzymes that break down collagen and thus assist in reducing wrinkles and the healing of skin tissues.

The examiner asserts that Schinitsky et al. teach a composition and method of reducing wrinkles comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%).

The examiner contends that Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate the entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule.

The examiner states that Bassford et al. teach methods of purifying ascorbic acid by dissolving the ascorbic acid in distilled water at 60°C and that for pharmaceutical preparations it is advisable to effect the final purification by crystallizing a first crop of pure material in the conventional manner asserted to be that in Experiment B.

The examiner states that Ptchelintsev discloses that topical application of an antioxidant, such as ascorbic acid, is effective in reducing redness, flushing and blushing associated with rosacea.

The examiner states that EP 0 771 557 discloses the use of ascorbic acid, preferably in the amount of 1 to 20%, for the treatment of acne, preferably at a pH of 2 to 5, particularly at a pH of 4.

The examiner takes the position that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose that at least 10% of the ascorbic acid is pretreated at particular temperatures and a pH of 3.5 to 4.1. However, the examiner alleges that it would have been obvious to modify the prior art with the expectation of facilitating entry into the skin for effective treatment of treating or protecting against skin damage due to exposure to the sun. The examiner asserts that the combination of references would have made obvious the purification of the ascorbic acid and the pH range claimed.

It is submitted that the amended claims are not obvious over the combination of six references cited by the examiner. ***The combination of references does not result in the invention as claimed.*** Bassford et al. is cited by the examiner for the alleged obviousness of the claimed pretreatment steps. However, Bassford et al. in Examples I and V show the purification of ascorbic acid by admixing ascorbic acid, water and an organic solvent, such as toluene, distilling off all of the water and recovering the ascorbic acid as crystals from the organic solvent. The instant claims recite dissolving ascorbic acid in water at a temperature of between about 60°C to about 90°C to provide an aqueous ascorbic acid solution of at least 20% (w/v); and cooling the aqueous ascorbic solution to below about 40°C to provide a concentrated ascorbic acid solution, which is utilized in the preparation of the claimed composition. Bassford et al. does not teach such a method and does not make it obvious. Bassford et al. always utilize an organic solvent and distill off the water and then crystallize from the organic solvent.

The examiner seems to be suggesting for the preparation of pharmaceuticals that Bassford et al. also teach Experiment B, in which Bassford et al. recovers crystalline ascorbic acid from an aqueous solution. However, it is clear from the Example V of Bassford et al. that it does not teach the pretreatment step as claimed and also that Experiment B is not an effective

process. Bassford et al. teach away from this process since they indicate that the Bassford et al. process loses 14 to 15 % of the ascorbic acid and results in decomposition and discoloration of the ascorbic acid (column 3, lines 45-48). Moreover, Experiment B does not suggest recovering a concentrated solution of ascorbic acid and using that in making preparations. Rather, Bassford et al. always teach recovering the ascorbic acid in a crystalline form.

The presently claimed compositions are neither taught nor suggested by the combined prior art references applied by the examiner.

Thus, for the reasons described above, the combined prior art does not teach or make obvious the claimed invention. It is therefore respectfully requested that the rejection of claims 25-27 under 35 U.S.C. § 103(a) be withdrawn.

V. Claims Rejections Under 35 U.S.C. § 103(a)

Claims 25-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Murad in view of Schinitsky et al., Darr et al., Bassford et al., Ptchelintsev and EP 0 771 557.

The examiner's assertions about the teachings of Murad, Schinitsky et al., Bassford et al., Ptchelintsev and EP 0 771 557 are set forth above and not repeated to avoid repetition.

The examiner states that Darr et al. disclose that ascorbic acid's activity as an antioxidant is beneficial as a pharmaceutical for treating the adverse changes in the skin but that it is unstable. The examiner states that Darr et al. teach that a pH of no more than 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form, facilitates entry into the skin and stabilizes the molecule. The examiner asserts that a 5% solution of ascorbic acid remains quite stable even at a pH of 4.5.

The examiner alleges that that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose that at least 10% of the ascorbic acid is pretreated at particular temperatures and a pH of 3.5 to 4.1. However, the examiner alleges that it would have been obvious to modify the prior art with the expectation of facilitating entry into the skin for an effective method of treating or protecting against skin damage due to exposure to the sun. The examiner asserts that the combination of references would have made obvious the purification of the ascorbic acid and since the pH range claimed is close enough to that disclosed in the prior art, it would have been obvious to adjust to the claimed pH range.

It is submitted that the amended claims are not obvious over the combination of six references cited by the examiner. ***The combination of references does not result in the invention as claimed.*** Bassford et al. is cited by the examiner for the alleged obviousness of the claimed pretreatment steps. However, Bassford et al. in its Examples I and V show the purification of ascorbic acid by admixing ascorbic acid, water and an organic solvent, such as toluene, distilling off all of the water and recovering the ascorbic acid as crystals from the organic solvent. As stated above, the instant claims recite dissolving ascorbic acid in water at a temperature of between about 60°C to about 90°C to provide an aqueous ascorbic acid solution of at least 20% (w/v); and cooling the aqueous ascorbic solution to below about 40°C to provide a concentrated ascorbic acid solution, which is utilized in the preparation of the claimed composition. Bassford et al. does not teach such a method and does not make it obvious. Bassford et al. always utilize an organic solvent and distill off the water and then crystallize from the organic solvent.

The examiner seems to be suggesting for the preparation of pharmaceuticals that Bassford et al. also teach Experiment B which recovers crystalline ascorbic acid from an aqueous solution. However, it is clear from Bassford's Example V that it does not teach the pretreatment step as claimed and also that Experiment B is not an effective process. Bassford et al. teach away from this process since they indicate that the Bassford et al. process loses 14 to 15 % of the ascorbic acid and results in decomposition and discoloration of the ascorbic acid (column 3, lines 45-48). Moreover, Experiment B does not suggest recovering a concentrated solution of ascorbic acid and using that in making preparations. Rather, Bassford et al. always teach recovering the ascorbic acid in a crystalline form.

Darr et al. teach that the pH should be no more than 3.5 to provide a stable preparation and thus teaches away from the instantly claimed pH ranges. The examiner asserts that in Darr et al. even at high pHs, such as 4.2 or 4.5, the ascorbic acid remains stable. That section of Darr et al. does indicate some stability for 12 weeks when stored in the dark at 4° C in capped microcentifuge tubes. Such conditions are not consistent with conditions of typical usage. Moreover, it also shows that the compositions yellow under these optimum storage conditions at these pHs.

The presently claimed compositions are neither taught nor suggested by the combined prior art references applied by the examiner.

Thus, for the reasons described above, the combined prior art does not teach or make obvious the claimed invention. It is therefore respectfully requested that the rejection of claims 25-27 under 35 U.S.C. § 103(a) be withdrawn.

VI. Claims Rejections Based on Obviousness Double Patenting

Claims 25-27 are rejected on the ground of obviousness-type double patenting as being obvious over claim 7 of U.S. Patent No. 6,217,914 in view of Bassford et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557.

The Examiner asserts that Claim 7 of 6,217,914 ('914) discloses a topical composition comprising at least about 5% (w/v) ascorbic acid, water, having a pH which is adjusted to about 3.6 to 4.1 wherein at least about wt. 10% of the total ascorbic acid is pretreated ascorbic acid and the pretreated ascorbic acid is produced by dissolving at least about 20% (w/v) ascorbic acid in water and heating to 60° 90° C, and wherein the composition further contains glucosamine.

The Examiner sates that Bassford et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557 are cited for the same reasons as above and incorporated to avoid repetition.

The Examiner states that the difference between the claimed composition and the claims of the present application is that claim 7 of the U.S. Patent does not expressly disclose cooling the pretreated solution to less than about 40 degrees Celsius or treatment of rosacea or acne. However, the examiner asserts that the prior art suggests that ascorbic acid is effective for the treatment of rosacea, acne and hypersensitivity conditions. Further, he states that the prior art discloses the preparation of ascorbic acid for pharmaceutical use by dissolving ascorbic acid in water at 60° C and cooling, for example to 15° C. Thus, the examiner asserts that it would have been obvious to modify the prior art with the expectation that it would facilitate the entry of the ascorbic acid into the skin and one would have been motivated to use the process of Bassford et al. with the expectation of obtaining a pure product for pharmaceutical uses.

However, as pointed out above ***the combination of references does not result in the invention as claimed***. Bassford et al. is cited by the examiner for the alleged obviousness of the claimed pretreatment steps. However, Bassford et al. in its Examples I and V show the purification of ascorbic acid by admixing ascorbic acid, water and an organic solvent, such as

toluene, distilling off all of the water and recovering the ascorbic acid as crystals from the organic solvent. As stated above, the instant claims recite dissolving ascorbic acid in water at a temperature of between about 60°C to about 90°C to provide an aqueous ascorbic acid solution of at least 20% (w/v); and cooling the aqueous ascorbic solution to below about 40°C to provide a concentrated ascorbic acid solution, which is utilized in the preparation of the claimed composition. Bassford et al. does not teach such a method and does not make it obvious. Bassford et al. always utilize an organic solvent and distill off the water and then crystallize from the organic solvent.

Thus, for the reasons set forth above, the claims are not obviousness-type double patenting over '914. It is therefore respectfully requested that the rejection of claims 25 - 27 under obviousness double patenting be withdrawn.

VII. Claims Rejections Based on Obviousness Double Patenting

Claims 25 and 26 are rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 6, 14 and 20 of U.S. Patent No. 6,444,699 in view of Setnikar et al. The Examiner states that claims 6, 14 and 20 of 6,444,699 ('699) disclose a composition having a pH of 3.6 to 4.2, water, 5 to25% (w/v) pretreated ascorbic acid and an aminosugar anti-inflammatory compound. The term "pretreated" is defined by the Specification to mean ascorbic acid which has been dissolved in water at about 60° to 90° C to form a concentrated solution which contains at least 20% (w/v) ascorbic acid and cooled to below about 40° C (col. 5, lines 10-26). The Examiner states that Setnikar et al. disclose that gluscosamine is an aminosugar having a pharmacological therapeutic index with respect to anti-inflammatory activity. Thus, the examiner states that the difference between the claims and '699 and the claims of the instant application is that '699 does not disclose glucosamine as the aninosugar. The examiner says that the prior art discloses that glusosamine has anti-inflammatory activity and thus the modification of claims 6, 14 and 20 of '699 would have been obvious.

Claims 25 and 26 of the instant application, however, are directed to a composition and claims 6, 14 and 20 of '699 are drawn to a method of treating. These statutorily different types of claims are not claiming the same thing and thus do not represent obviousness double patenting.

Thus, for the reasons set forth above, the claims are not obviousness-type double patenting over '699. It is therefore respectfully requested that the rejection of claims 25 and 26 under obviousness double patenting be withdrawn.

Applicant reserves the right to later file a terminal disclaimer.

CONCLUSION

In light of the remarks set forth above, it is believed that the pending claims are in condition for allowance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Attorney Docket No. 36091-701.501).

Respectfully submitted,

Date June 27, 2008 By: Esther M Kepplinger

Esther M. Kepplinger
Director, Patent Operations
Registration No. 57,243

WILSON SONSINI GOODRICH & ROSATI, PC
650 Page Mill Road
Palo Alto, CA 94304-1050
Direct Line: (202) 973-8810
FAX; (650) 493-6811
Client No. 021971